

ANDA 74-530

April 21, 2000

Zenith Goldline Pharmaceuticals, Inc.
Attention: Patricia Jaworski
140 Legrand Avenue
Northvale, NJ 07647

Dear Madam:

This is in reference to your abbreviated new drug application dated August 1, 1994, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Terazosin Hydrochloride Tablets, 1 mg (base), 2 mg (base), 5 mg (base) and 10 mg (base).

Reference is also made to our Tentative Approval letter dated August 14, 1998, and to your amendments dated November 9, 1999; and January 14, February 9, March 22, and March 24, 2000.

The listed drug product (RLD) referenced in your application, Hytrin® Tablets of Abbott Laboratories, is subject to periods of patent protection which expire on April 29, 2013, (U.S. Patent No. 5,412,095 [the '095 patent], and U.S. Patent No. 5,504,207 [the '207 patent]). Your application contains patent certifications to each of these patents under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, or sale of this drug product will not infringe on either patent. Section 505(j)(5)(B)(iii) of the Act provides that approval of an abbreviated application shall be made effective immediately unless an action is brought for infringement of the patents which are the subject of the certifications before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. You have notified the Agency that Zenith Goldline Pharmaceuticals (Zenith Goldline) has complied with the requirements of Section 505(j)(2)(B) of the Act by providing the required notice to each patent holder, and that no action for patent infringement was brought against Zenith Goldline within the statutory forty-five day period. Furthermore, in accordance with 21 CFR 314.94(a)(12)(vi), Zenith Goldline is not required to submit

patent certifications for U.S. Patent Nos. 5,212,176, and 5,294,615.

In addition, the Act provides that an abbreviated application that contains a certification described in section 505(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification") and that is for a drug for which a previous abbreviated application has been submitted, that also contains a Paragraph IV Certification, shall be made effective not earlier than one hundred and eighty days after (1) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or (2) the date of a decision of a court holding the patent which is the subject of the certification to be invalid or not infringed, whichever event occurs first {Section 505(j)(5)(B)(iv)}.

However, as noted in the Agency's publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), an abbreviated new drug application for this drug product was approved for Geneva Pharmaceuticals Inc. (Geneva) on December 31, 1998. This application also contained a Paragraph IV Certification and was the first application received by the Agency for this drug product. Consequently, Geneva became eligible for 180 days of market exclusivity commencing on the date of first commercial marketing. On March 23, 2000, Geneva notified the Agency that Geneva had relinquished any period of exclusivity to which it was entitled for Terazosin Tablets.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Terazosin Hydrochloride Tablets, 1 mg (base), 2 mg (base), 5 mg (base) and 10 mg (base), to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Hytrin® Tablets, 1 mg (base), 2 mg (base), 5 mg (base) and 10 mg (base), respectively, of Abbott Laboratories). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy that you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

Gary Buehler
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research

APPROVAL